

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA

GILEAD SCIENCES, INC. and
EMORY UNIVERSITY,

Plaintiffs,

v.

// CIVIL ACTION NO. 1:14CV99
(Judge Keeley)

MYLAN INC. and MYLAN
PHARMACEUTICALS INC.,

Defendants.

**MEMORANDUM OPINION AND ORDER OVERRULING THE PLAINTIFFS'
OBJECTIONS [DKT. NO. 195] AND AFFIRMING THE
ORDER OF THE MAGISTRATE JUDGE [DKT. NO. 190]**

On July 14, 2015, the plaintiffs, Gilead Sciences, Inc. and Emory University (collectively, "Gilead"), objected to the Order of the Honorable John S. Kaull, United States Magistrate Judge, denying its motion to compel. For the reasons that follow, the Court **OVERRULES** Gilead's objections (Dkt. No. 195) and **AFFIRMS** the Order (Dkt. No. 190).

BACKGROUND

This patent infringement lawsuit, filed by Gilead on June 9, 2014, arises under the Drug Price Competition and Patent Term Restoration Act. See 21 U.S.C. §§ 355, 360cc; 35 U.S.C. §§ 156, 271. Gilead contends that the defendants, Mylan Inc. and Mylan Pharmaceuticals, Inc. (collectively, "Mylan"), infringed four patents-in-suit by filing an Abbreviated New Drug Application ("ANDA") seeking United States Food and Drug Administration approval to market a generic version of Gilead's Truvada®.

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On November 19, 2014, Gilead served Mylan with its first set of requests for document production. Mylan objected to some of those requests on December 22, 2014. More than six months later, on May 28, 2015, Gilead filed a motion seeking to compel Mylan to produce (1) documents relating to Mylan's development of the final formulation of its ANDA product; (2) documents evidencing certain communications between Mylan and Teva regarding the patents-in-suit, a TDF/FTC combination product, and this litigation; and, (3) documents relating to market analysis or investigation for a TDF/FTC communication product (Dkt. No. 160 at 2).

Mylan opposed Gilead's motion to compel, arguing the motion was moot because it had already produced all documents relating to the patents-in-suit (Dkt. No. 176 at 1). Mylan alleged that, to the extent Gilead sought documents relating to its PEPFAR ANDA, which was not part of this case, it had failed to file a timely motion to compel.¹ *Id.* at 2. The PEPFAR ANDA, ANDA No. 90-049, covers a product which, according to Mylan, is sold outside of the United States, has a "different formulation," and is "manufactured using a different process," making it irrelevant to the instant lawsuit (Dkt. No. 176 at 3). Gilead contended that documentation

¹ PEPFAR is an abbreviation for the United States President's Emergency Plan for AIDS Relief.

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relating to the PEPFAR ANDA was relevant to Mylan's defense that Gilead's patents are invalid for lack of enablement (Dkt. No. 183 at 3). Because Mylan raised this "new theor[y]" for the first time on June 18, 2015, Gilead asserted that its motion to compel was timely.² Id.

The Court referred this discovery dispute to Magistrate Judge Kaull for resolution (Dkt. No. 161). After a thorough airing of the issues in briefing and oral argument, Magistrate Judge Kaull found that the discovery sought by Gilead was irrelevant and the motion to compel untimely (Dkt. No. 190). Specifically, he concluded that the PEPFAR ANDA materials were irrelevant to Mylan's invalidity defense, which "looks no further than the four corners of initial patent and patent application." Id. at 3. He also concluded that Gilead had been aware of Mylan's lack of enablement defense since August 12, 2014, when it appeared in Mylan's answer. Id. at 4. Because Gilead waited 158 days before filing its motion to compel, Magistrate Judge Kaull found that the motion was untimely and denied it. Id. at 5.

² Gilead does not explain how Mylan raised this defense for the first time on June 18, 2015; the docket, however, indicates that Mylan served supplemental responses to Gilead's interrogatories on that date (Dkt. Nos. 174, 175).

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Gilead objected to Magistrate Judge Kaull's Order, contending it was "premised on a fundamental misunderstanding of relevant patent law." (Dkt. No. 195 at 1). Gilead argued that the PEPFAR ANDA documents are directly relevant to whether Mylan was able to make "multiple, different stable fixed dose combinations of FTC and TDF without undue experimentation," an element of the lack of enablement defense. Id. at 3. It contended that Magistrate Judge Kaull's lack of timeliness ruling was "inextricably intertwined with the Order/Opinion's erroneous conclusion that the documents were not relevant . . . , but that, at any rate, it was unaware of Mylan's defense until June 18, 2015. Id. at 5.

In response, Mylan urged the Court to affirm the magistrate judge's Order because Gilead had failed to file a timely motion to compel under LR Civ. P. 37.02(b) (Dkt. No. 198 at 1). According to Mylan, Gilead's assertion that it was unaware of the relevance of the PEPFAR ANDA until June 18, 2015, is a tacit admission that its document requests seeking the PEPFAR materials had no basis at the time they were made. Id. at 2.

Mylan further contended that the PEPFAR ANDA materials are irrelevant to its lack of enablement defense because (1) the PEPFAR product is different from the product accused of infringement in the instant case; (2) the PEPFAR documents were generated years

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after the relevant time point for evaluating enablement; and, (3) Mylan's product is legally irrelevant to enablement. Id. at 7-8.

In replying to this argument, Gilead asserted that post-filing evidence of enablement can be relevant to whether the patent was enabling (Dkt. No. 203 at 2). It further contended that its motion to compel was timely because, until June 18, 2015, Mylan had "simply invoked 35 U.S.C. § 112 and/or the word 'enablement' as defenses." Id. The matter is fully briefed and ripe for disposition.

STANDARD OF REVIEW

The Court reviews a magistrate judge's non-dispositive pre-trial ruling for clear error. Shoop v. Hott, No. 5:08CV188, 2010 WL 5067567, at *2 (N.D.W. Va. Dec. 6, 2010) (Stamp, J.) ("[A] magistrate judge's ruling may be reversed only on a finding that the order is 'clearly erroneous or is contrary to law.'"); Fed. R. Civ. P. 72(a); 28 U.S.C. § 636(b)(1). A finding of clear error is only appropriate when, "although there is evidence to support it, the reviewing court on the entire evidence is left with a definite and firm conviction that a mistake has been committed." Shoop, 2010 WL 5067567, at *2 (internal quotation marks omitted) (quoting United States v. United States Gypsum Co., 333 U.S. 364, 395 (1948)). "In light of the broad discretion given to a magistrate

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judge in the resolution of nondispositive discovery disputes, the court should only overrule a magistrate judge's determination if this discretion is abused." Id. (citing Detection Sys., Inc. v. Pittway Corp., 96 F.R.D. 152, 154 (W.D.N.Y. 1982)).

ANALYSIS

After carefully considering Magistrate Judge Kaull's Order and the parties' briefing on both the motion to compel and the objections, the Court is convinced that the Order is not clearly erroneous. Shoop, 2010 WL 5067567, at *2. Magistrate Judge Kaull bifurcated his Order into two sections regarding both the substantive law behind Mylan's invalidity defense and timeliness (Dkt. No. 190 at 2-4). Notwithstanding Gilead's admonition that the two issues are "inextricably intertwined," the Court finds overwhelming evidence to affirm Magistrate Judge Kaull's ruling based on the timeliness issue, and need not address the invalidity defense.

In Mylan's answer, filed on August 12, 2014, it alleged that the patents-in-suit are invalid for failure to satisfy 35 U.S.C. § 112 (Dkt. No. 24 at 25).³ On November 19, 2014, Gilead served Mylan with discovery requests, including a request for "documents

³ Mylan reiterated this defense in its answer to the amended complaint, filed on February 9, 2015 (Dkt. No. 97 at 30).

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relating to the development of the final formulation of Mylan's ANDA product, including . . . attempts to develop a product employing a formulation other than that of Mylan's ANDA product, and all testing data concerning those formulations." (Dkt. No. 160 at 2). Gilead's document request defined "Mylan's ANDA product" as "the product for which Mylan Pharmaceuticals Inc. filed ANDA No. 20-6436." (Dkt. No. 176 at 3). Mylan responded to Gilead's document request on December 22, 2014, agreeing to produce all relevant, non-privileged documents except those relating to the PEPFAR ANDA. Id. at 2.

Gilead claims that it was unaware of Mylan's non-enablement defense until June 18, 2015 (Dkt. No. 302 at 2-3). This statement is belied by the fact that Gilead filed its motion to compel on May 28, 2015, three weeks before June 18, 2015 (Dkt. No. 160). Gilead, thus, seems to be alleging that it filed a motion to compel documents relating to the PEPFAR ANDA on May 28, although it was unaware of the specific details of Mylan's defense until three weeks later. As Mylan points out, this argument implies that Gilead's request for PEPFAR ANDA documents had no relevant basis when originally made in November, 2014 (Dkt. No. 198 at 6).

Gilead's argument, that it was unaware of the non-enablement defense until six months after it sought discovery related to the

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PEPFAR patents and three weeks after it filed a motion to compel that discovery, strains credulity. In this district, a motion to compel "is deemed waived" unless filed within thirty (30) days after the discovery response was due. LR Civ. P. 27.02(b). An exception exists if "failure to file the motion was caused by excusable neglect or by some action of the non-moving party." Id. Neither ground exists here. Gilead therefore waived its motion to compel by failing to file the same within thirty days after Mylan objected on December 22, 2014. Magistrate Judge Kaull's conclusion that Gilead's motion was untimely was not clearly erroneous. The Court therefore **AFFIRMS** the Order (Dkt. No. 190) and **OVERRULES** Gilead's objections (Dkt. No. 195).

It is so **ORDERED**.

The Court directs the Clerk to transmit copies of this Order to counsel of record.

DATED: September 22, 2015.

/s/ Irene M. Keeley

IRENE M. KEELEY
UNITED STATES DISTRICT JUDGE